STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	442615	A. BUILDING _____ B. WING _____	10/25/2012

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
FRESENIUS MEDICAL CARE WEST NASHVILLE	242 ORLANDO AVENUE NASHVILLE, TN 37209

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V 000	INITIAL COMMENTS A recertification survey was conducted 10/8/12 through 10/25/12. An entrance conference was conducted on 10/8/12 at 10:38 AM with the Operations Manager. A telephone exit conference was conducted at 10:10 AM on 10/25/12 with the Regional Vice President, Director of Operations, Technical Operations Manager, Regional Quality Manager, Director of Education, North Nashville Operations Manager, Clinic Manager, and Director of Regulatory Affairs. Based on review of facility policy, document review, QAPI minutes, By-laws, Governing Board minutes, medical record review, observation and interview, the facility was found to be out of compliance with the following Conditions for Coverage: 494.40 Water & Dialysate Quality, 494.60 Physical Environment, 494.80 Patient Assessment, 494.90 Patient Plan of Care, 494.110 Quality Assess and Performance Improvement, 494.150 Responsibilities of the Medical Director, and 494.180 Governance. The Conditions for Coverage 494.40 Water & Dialysate Quality, 494.60 Physical Environment, 494.90 Patient Plan of Care and 494.110 Quality Assess and Performance Improvement, 494.150 Responsibilities of the Medical Director and 494.180 Governance citations resulted in a SERIOUS AND IMMEDIATE THREAT to the health and safety of all patients receiving hemodialysis at the facility and were cited as IMMEDIATE JEOPARDY. The following abbreviations were used in the statement of deficiencies:	V 000		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE

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& - and
> - greater than
< - less than
AED - Automatic External Defibrillator
AM - before noon
Approx - approximately
bicarb - bicarbonate
BP - blood pressure
cc - cubic centimeters
cfu - colony forming unit
CMS - Centers for Medicare & Medicaid Services
c/o - complaint of
CPR - cardiopulmonary resuscitation
DBP - diastolic blood pressure
DI - Deionization
dist - distribution
DOO - director of operations
ER - emergency room
EU - Endotoxin Unit
H - hour
H2O - water
Hct - hematocrit
HD - hemodialysis
Hgb - hemoglobin
Hr - hour
IDT - Interdisciplinary Team
LPN - Licensed Practical Nurse
MD - Medical Doctor
mg - milligrams
ml - milliliter
min - minimum
NS - normal saline
P - pulse
PCT - Patient Care Technician
PM - after noon
PO - by mouth
POC - plan of care
Pt/pt - patient

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V 000	Continued From page 2 QAI - Quality Assessment Improvement QAPI - Quality Assessment Performance Improvement RN - Registered Nurse RO - reverse osmosis RP - Random Patient SBP - systolic blood pressure SW - Social Worker sys - system tech - technician TRMT - treatment u - units uf - ultrafiltration VS - vital signs WDS - water delivery system	V 000		
V 111	494.30 IC-SANITARY ENVIRONMENT The dialysis facility must provide and monitor a sanitary environment to minimize the transmission of infectious agents within and between the unit and any adjacent hospital or other public areas. This STANDARD is not met as evidenced by: Based on observation and interview, the facility failed to maintain a clean and sanitary environment as evidenced by untidy and soiled conditions inside the water treatment room for 2 of 4 (10/15/12 and 10/16/12) observation days. The findings included: 1. Observations in the water treatment room on 10/15/12 and 10/16/12 revealed the following: A hose with an open end was connected to the bicarbonate distribution tank and looped over the pump mixer. The piping from the water source had insulation	V 111		

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V 111	Continued From page 3 exposed. White substances were noted around the bicarbonate tanks and the flooring around the tanks. The walls behind the acid storage tanks had a build-up of grime and dust. A copper pipe behind the acid tank had thick green build-up around the outside of the pipe. Brown streaks were noted on the walls behind and above the primary acid tank and a piece of wall missing. 2. During an interview in the water room on 10/15/12 at 4:25 PM, the Biomed Technician stated, "...If I mixed the bicarb, I would clean up afterwards..." 3. During an interview in the water room on 10/16/12 at 12:00 PM, the Technical Supervisor verified the water room was very dusty.	V 111		
V 117	494.30(a)(1)(i) IC-CLEAN/DIRTY;MED PREP AREA;NO COMMON CARTS Clean areas should be clearly designated for the preparation, handling and storage of medications and unused supplies and equipment. Clean areas should be clearly separated from contaminated areas where used supplies and equipment are handled. Do not handle and store medications or clean supplies in the same or an adjacent area to that where used equipment or blood samples are handled. When multiple dose medication vials are used (including vials containing diluents), prepare individual patient doses in a clean (centralized) area away from dialysis stations and deliver separately to each patient. Do not carry multiple	V 117		

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V 117	Continued From page 4 dose medication vials from station to station. Do not use common medication carts to deliver medications to patients. If trays are used to deliver medications to individual patients, they must be cleaned between patients. This STANDARD is not met as evidenced by: Based on observation and interview, the facility failed to maintain a clean area for storage of supplies. The findings included: During a tour of the facility treatment area on 10/15/12 beginning at 2:39 PM, the following was observed in a cabinet under the sink in Bay 1: Betadine, air freshener, lotion, blood glucose test strips, glucose monitoring control solution, a ziplock bag of blood collection tubes, disinfectant spray and a patient alarm to detect wetness. During an interview on 10/15/12 at 2:39 PM, PCT #4 stated the cabinet was a "catch all."	V 117		
V 175	494.40 CFC-WATER & DIALYSATE QUALITY This CONDITION is not met as evidenced by: Based on review of facility Bylaws, policy, disinfection logs, culture and endotoxin reports, observation and interview, the facility failed to ensure the Medical Director was responsible for ensuring the water treatment and dialysate preparation equipment and distribution systems were maintained in a manner that provided an acceptable quality of water for preparation of dialysate, failed to ensure the salt pellets were	V 175		

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V 175	Continued From page 5 maintained above the level of the brine solution in the tank, failed to ensure the disinfection program was effective to ensure bacteria levels remained below allowed contamination and failed to ensure a corrective action plan was developed and implemented to prevent the recurrent growth of bacteria in the water treatment system for 19 of 19 (4/2011, 5/2011, 6/2011, 7/2011, 8/2011, 9/2011, 10/2011, 11/2011, 12/2011, 1/2012, 2/2012, 3/2012, 4/2012, 5/2012, 6/2012, 7/2012, 8/2012, 9/2012, and 10/2012) months reviewed. The facility's failure to ensure acceptable water quality for the provision of hemodialysis treatment resulted in a SERIOUS AND IMMEDIATE THREAT to the health and safety of all hemodialysis patients and placed them at risk for serious infection and death. The findings included: 1. The Medical Director failed to assure interventions were developed and implemented to maintain water contamination levels below the action level to provide safe hemodialysis treatments. Refer to V 179. 2. The facility failed to ensure the salt pellets were maintained above the level of the brine solution in the tank. Refer to V 190. 3. The facility failed to ensure an effective corrective action plan was developed and implemented to determine the root cause and to control the elevated water culture and endotoxin levels.	V 175		

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V 175	Continued From page 6 Refer to V 274.	V 175		
V 179	494.40(a) BACT OF H20-MEDICAL DIRECTOR RESPONSIBLE 4.1.2 Bacteriology of water: med dir resp The facility medical director is responsible to ensure the manufacturer or supplier of a complete water treatment and distribution system demonstrates that the complete water treatment, storage, and distribution system is capable of meeting these requirements at the time of installation Following installation of a water treatment, storage, and distribution system, the user is responsible for continued monitoring of the water bacteriology of the system and for complying with the requirements of this standard, including those requirements related to action levels. This STANDARD is not met as evidenced by: Based on facility Bylaw and policy review, culture and endotoxin reports, disinfection logs and interview, the Medical Director failed to demonstrate responsibility for maintaining water treatment and diaysate preparation equipment and distribution systems that provided water used to prepare dialysate within allowable limits to ensure the safety of the patients receiving hemodialysis for 19 of 19 (4/2011, 5/2011, 6/2011, 7/2011, 8/2011, 9/2011, 10/2011, 11/2011, 12/2011, 1/2012, 2/2012, 3/2012, 4/2012, 5/2012, 6/2012, 7/2012, 8/2012, 9/2012, and 10/2012) months reviewed. The Medical Director's failure to demonstrate responsibility for maintaining the water treatment system placed all the patients receiving	V 179		

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V 179	Continued From page 7	V 179		

hemodialysis at risk of exposure to contaminated water and resulted in a SERIOUS AND IMMEDIATE THREAT to their health and safety.

The findings included:

Review of the facility's Bylaws revealed, "...Medical Director Duties. The Medical Director is directly and actively responsible for the creation, on-going improvement and preservation of high quality professional care of patients at the Facility. The Medical Director is responsible for planning, organizing, conducting and directing the professional services of the Facility and, to that end, has specific duties and authorities...The Medical Director is responsible for the delivery of patient care and outcomes in the Facility and is accountable to the Company [company initials], Medical Department, Governing Body and CMS, for the quality of medical care provided to patients... Ensure that all policies and procedures relative to patient admissions, patient care (including, but not limited to, patient comprehensive assessments, plans of care and patient rights and responsibilities), infection control, and safety are made available to all medical staff members and non-physician practitioners and that they are adhered to by all individuals who treat patients in the Facility..."

Review of the facility's policy, "Microbiological Monitoring of Water Used for Dialysis Purposes", documented, "....Water cultures will be monitored using the following action level and allowable limits; Bacteria RO or DI Product - Action level 20 CFU/ml and Allowable limit 50 CFU/ml. Bacteria RO Distribution - Action level 50 CFU/ml and Allowable limit 200 CFU/ml. Endotoxin RO

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V 179	Continued From page 8 or DI Product Action level .25 EU/ml and Allowable level 1 EU/ml. Endotoxin RO Distribution - Action level 1 EU/ml and Allowable limit 2 EU/ml... Test results exceeding the Action Level or allowable limits - Promptly (within 48 hours) notify the Medical Director...Discuss with Medical Director, the creation of an action plan when test results indicate that the "Allowable limits" have been exceeded..." Review of the bacterial cultures and endotoxin testing results and disinfection logs for the water treatment system during the months of 4/11, 5/11, 6/11, 7/11, 8/11, 9/11, 10/11, 11/11, 12/11, 1/12, 2/12, 3/12, 4/12, 5/12, 6/12, 7/12, 8/12, 9/12 and 10/12 revealed culture and/or endotoxin levels outside the allowable and/or action limits as follows: 4/2011 - Pre-disinfection samples drawn on 4/3/11 revealed water cultures and endotoxin levels were < the action level. The water treatment system was disinfected by the facility on 4/3/11 and 4/4/11. Following this disinfection the water culture samples drawn on 4/6/11 were > the allowable limit. The water treatment system was disinfected again on 4/17/11. The post-disinfection samples drawn on 4/20/11 continued to have water culture > the allowable limit. There was no documentation the Medical Director reviewed and monitored the elevated water cultures during the month of April 2011. 5/2011 - Pre-disinfection samples drawn on 5/1/11 had endotoxin level > the action level. The water treatment system was disinfected 5/1/11.	V 179		

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V 179	Continued From page 9 The post-disinfection samples drawn 5/4/11 revealed the endotoxin levels continued to be > the action level. Pre-disinfection samples drawn 5/13/11 had endotoxin level > action level. The water treatment system was disinfected 5/15/11. The post-disinfection samples drawn on 5/18/11 continued to have endotoxin level > the action level. There was no documentation of further disinfection or action plans for the continued elevated endotoxin levels on 5/4/11 and 5/18/11. The pre-disinfection samples drawn on 5/27/11 had endotoxin level at the action level. The water treatment system was disinfected on 5/29/11. Review of the facility hemodialysis schedules and treatment records revealed patients continued to dialyze during the month of May with the elevated endotoxin levels. There was no documentation the Medical Director had reviewed and monitored the elevated endotoxin levels during the month of May 2011. 6/2011 - Post-disinfection samples drawn 6/1/11 had water culture and endotoxin levels > the allowable limit. The water treatment system was disinfected 6/12/11. Post-disinfection sample on 6/15/11 had a water culture > the allowable limit. The disinfection log documented, "... 6/17/11 Due to improving results, disinfect schedule changed to every three weeks ..." Water cultures on 6/29/11 had > action level and > allowable limit. There was no documentation if the samples drawn on 6/29/11 were pre-disinfection or post-disinfection. There was no documentation the Medical Director had reviewed and monitored the elevated water culture and endotoxin levels during the month of	V 179		

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V 179	Continued From page 10 June 2011. 7/2011 - Pre-disinfection samples drawn on 7/3/11 had water culture levels > the allowable limit, and endotoxin level > action level. The water treatment system was disinfected 7/3/11. Post-disinfection samples drawn on 7/7/11 continued to have water cultures > action level and > the allowable limit. There was no documentation of further action plans or disinfection for the continued elevated water cultures. A water sample drawn on 7/12/11 had a water culture > the allowable limit. Pre-disinfection samples drawn 7/22/11 had water cultures > the action limit and > the allowable limit. The water sample also had endotoxin levels > the action level. The water treatment system was disinfected on 7/24/11. There was no documentation the Medical Director had monitored the elevated water culture and endotoxin levels during the month of July 2011. 8/2011 - A water sample drawn 8/12/11 had water cultures > the allowable limits, and endotoxin > the action level. The water treatment system was disinfected on 8/21/11. There was no documentation the Medical Director reviewed and monitored the elevated water culture and endotoxin levels during the month of August 2011. 9/2011 - Pre-disinfection samples drawn on 9/11/11 had water cultures > the action level. The water treatment system was disinfected. There was no documetation the Medical Director	V 179		

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had reviewed and monitored the elevated water culture and endotoxin levels during the month of September 2011.

10/2011 - Pre-disinfection samples drawn 10/16/11 had culture > the action level and endotoxin level > allowable limits. The water treatment system was disinfected 10/16/11.

There was no documentation the Medical Director had reviewed and monitored the elevated water cultures and endotoxin levels during month of October 2011.

11/2011 - Pre-disinfection samples drawn 11/25/11 revealed the GRNFLO-FEED-BEFORE sample port water culture was 92 CFU/ml . The water treatment system was disinfected 11/27/11. Post-disinfection samples drawn 11/30/11 revealed: RO, 1 permeate sample port water culture was 180 CFU/ml, the endotoxin level was 0.43 EU/ml.

There was no documentation the Medical Director had reviewed and monitored the elevated water culture and endotoxin levels during the month of Novemeber 2011.

12/2011 - Water samples drawn 12/7/11 revealed the RO, 1 permeate sample port water endotoxin level was 0.40 EU/ml. Pre-disinfection samples drawn 12/18/11 revealed the RO 1, permeate sample port water endotoxin was 0.39 EU/ml. The water treatment system was disinfected 12/18/11. Post-disinfect water samples drawn 12/20/11 revealed the RO 1, permeate sample port water endotoxin level was 0.26 EU/ml. Water samples drawn 12/27/11 revealed the RO

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V 179	Continued From page 12 1, permeate sample port water endotoxin level was 0.26 EU/ml. There was no documentation the Medical Director had reviewed and monitored the elevated endotoxin during the month of December 2011. 1/2012 - Pre-disinfection samples drawn 1/13/12 revealed the Acid mixer 1, feed sample port water culture was 116 CFU. H2O Delivery System (WDS) 1, Ultrafilter pre 1 sample port water culture was 56 CFU/ml. The Acid Mixer 1, feed sample port water culture was 116 CFU/ml. The water treatment system was disinfected 1/15/12. Post-disinfection samples drawn 1/18/12 revealed the RO 1, permeate sample port water endotoxin level was 0.27 EU/ml. A water sample drawn 1/27/12 revealed the Acid mixer 1, feed sample port water culture was 166 CFU/ml. RO 1, permeate sample port water culture was 120 CFU/ml. A leak in the loop was repaired and the water treatment system was disinfected 1/29/12. A water sample drawn 1/30/12 revealed the Acid mixer 1, feed sample port water endotoxin level was 4.56 EU/ml. H2O delivery system (WDS) 1, Ultrafilter pre 1 sample port water culture was 50 CFU/ml, the endotoxin level was 1.81 EU/ml. Solution Delivery System (SDS) End of Loop sample port water endotoxin level was 1.17 EU/ml. A water sample drawn 1/31/12 revealed the RO 1, permeate sample port water endotoxin level was 0.36 EU/ml. There was no documentation the Medical Director had reviewed and monitored the elevated water culture and endotoxin levels during the month of January 2012.	V 179		

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V 179	Continued From page 13 2/2012 - Pre-disinfection samples drawn 2/9/12 revealed the Acid mixer 1, feed sample port water culture was 142 CFU/ml. H2O Delivery system (WDS) 1, ultrafilter pre 1 sample port water endotoxin level was 0.50 EU/ml. RO 1, permeate sample port water endotoxin level was 0.35 EU/ml. RO 2, polished sample port water endotoxin level was 0.32 EU/ml. Acid mixer 1, feed sample port water culture was 142 CFU/ml. The water treatment system was disinfected 2/12/12. Post-disinfection samples drawn 2/15/12 revealed the RO 1, polished sample port water endotoxin level was 0.56 EU/ml. RO 1, permeate sample port water endotoxin level was 0.45 EU/ml. Pre-disinfection samples drawn 2/26/12 revealed the RO 1, permeate sample port water endotoxin level was 0.32 EU/ml. Acid mixer 1, feed sample port water culture was 90 CFU/ml. A Granuflo conversion kit was installed, and the water treatment system was disinfected 2/26/12. Post-disinfection samples drawn 2/29/12 revealed the RO 1, permeate sample port water endotoxin level was 0.58 EU/ml. There was no documentation the Medical Director had reviewed and monitored the elevated water culture and endotoxin levels during the month of February 2012. 3/2012 - Pre-disinfection samples drawn 3/11/12 were unable to be processed by the laboratory. The water treatment system was disinfected 3/12/12. Post-disinfection samples drawn 3/14/12 revealed the RO 1, permeate sample port water endotoxin level was 0.66 EU/ml. A repeat sample drawn 3/28/12 revealed RO 1, polished sample port water endotoxin level was 1.00 EU/ml. RO 1, permeate sample port water	V 179		

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V 179	Continued From page 14 endotoxin level was 0.93 EU/ml. There was no documentation the Medical Director had reviewed and monitored the elevated endotoxin levels during the month of March 2012. 4/2012 - Pre-disinfection samples drawn 4/3/12 revealed the RO 1, permeate sample port water endotoxin level was 1.86 EU/ml. RO 1, polished sample port water endotoxin level was 1.58 EU/ml. The water treatment system was disinfected 4/3/12. Post-disinfection samples drawn 4/4/12 revealed the RO 1, permeate sample port water endotoxin level was 0.69 EU/ml. The water treatment system sample ports were flushed with alcohol on 4/9/12. A validation sample drawn 4/10/12 revealed the RO 1, polished sample port water culture was > 200 CFU/ml. Pre-disinfection samples drawn 4/12/12 - Ultrafilter 1, feed sample port water culture was > 200 CFU/ml. Distribution loop 1, feed sample port water culture was 164 CFU/ml. The water treatment system was disinfected 4/15/12. Post-disinfection samples drawn 4/17/12 revealed the Distribution loop 1, return sample port water endotoxin level was 0.96 EU/ml. RO 1, permeate sample port water endotoxin level was 0.40 EU/ml. Repeat samples drawn 4/24/12 revealed the RO 1, permeate sample port water endotoxin level was 0.50 EU/ml. HD machine 3, outlet sample port water culture was 58 CFU/ml. The sample port of the RO 1, permeate was disinfected on 4/26/12. Post-disinfection sample drawn 4/26/12 revealed the RO 1, permeate sample port water endotoxin level was 0.84 EU/ml. Ultrafilter 1, feed sample port water the endotoxin level was 1.04 EU/ml.	V 179		

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V 179	Continued From page 15 There was no documentation the Medical Director had reviewed and monitored the elevated water culture and endotoxin level reports dated 4/3/12, 4/4/12, 4/10/12, 4/17/12, and 4/26/12 during the month of April 2012. 5/2012 - A sample drawn 5/1/12 revealed the RO 1, permeate sample port water endotoxin level was 0.54 EU/ml. Distribution loop 1, return sample port water culture was 182 CFU/ml. Ultrafilter 1, feed sample port water culture was 160 CFU/ml. A repeat sample drawn 5/10/12 revealed the Distribution loop 1, return sample port water culture was > 200 EU/ml. Ultrafilter 1, feed sample port water culture was > 200 CFU/ml. RO 1, permeate sample port water endotoxin level was 0.53 EU/ml. Distribution loop 1, return sample port water culture was > 200. Ultrafilter 1, feed sample port water culture > 200 CFU/ml. The sample ports were moved and a leak in the water loop was repaired 5/12/12. The water treatment system was disinfected 5/13/12. Post-disinfection samples drawn 5/15/12 revealed the Ultrafilter 1, feed sample port water endotoxin level was 1.68 EU/ml. RO 1, permeate sample port water endotoxin level was 0.69 EU/ml. Distribution loop 1, return sample port water endotoxin level was 2.06 EU/ml. Acid mixer 1, feed sample port water endotoxin level was 2.68 EU/ml. Ultrafilter 1, outlet sample port water endotoxin level was 1.28 EU/ml. Bicarb mixer 1, feed sample port water endotoxin level was 2.22 EU/ml. A leak in the water loop was repaired, and the tank and loop was disinfected 5/16/12. Repeat water samples drawn 5/18/12 revealed the RO 1, permeate sample port water endotoxin level was 0.65 EU/ml. Acid mixer 1, feed sample port water endotoxin level was 1.19 EU/ml. The	V 179		

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tank and loop were disinfected 5/23/12. Post-disinfection samples drawn 5/25/12 revealed the RO 1, permeate sample port water endotoxin was 0.61 EU/ml. Ultrafilter 1, feed sample port water culture was > 200 CFU/ml, the endotoxin level was 0.98 EU/ml. Pre-disinfection samples drawn 5/30/12 revealed the Bicarb dist sys, return sample port water culture was > 200 CFU/ml, the endotoxin level was 1.01 EU/ml. RO 1, permeate sample port water endotoxin level was 0.94 EU/ml. Distribution loop 1, return sample port water culture was 64 CFU/ml. Ultrafeed 1, feed sample port water culture was > 200 CFU/ml, the endotoxin level was 1.07 EU/ml. The tank and loop were disinfected 5/30/12.

There was no documentation the Medical Director had reviewed and monitored the elevated water culture and endotoxin levels during the month of May 2012.

6/2012 - Pre-disinfection samples drawn 6/1/12 revealed the RO 1, permeate sample port water endotoxin level was 0.58 EU/ml. Ultrafilter 1, feed sample port water culture was > 200 CFU/ml. Bicarb mixer 1, feed sample port water culture was 140 CFU/ml. The DI bypass hoses, pump outlet hose, post UF sample port, bicarb feed sample port, were replaced, and leaks to DI monitor were repaired. The water treatment system was disinfected 6/3/12. Post-disinfection samples drawn 6/5/12 revealed the Sample port 2, outlet water culture was 110 CFU/ml. Sample port 3, outlet water culture was > 200 CFU/ml, the endotoxin level was 1.23 EU/ml. Sample port 4, outlet water culture was > 200 CFU/ml. Sample port 5, outlet water culture was > 200 CFU/ml. Sample port 6, outlet water culture was 70

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CFU/ml. Sample port 7, outlet water culture was 128.0 CFU/ml. Repeat samples drawn 6/14/12 revealed the RO 1, polished sample port water endotoxin level was 1.14 EU/ml. Sample port 1, outlet sample port water culture was 70 CFU/ml, the endotoxin level was 9.60 EU/ml. Sample port 2, outlet, endotoxin level was 4.24 EU/ml. Sample port 3, outlet water endotoxin level was 1.70 EU/ml. Sample port 4, outlet, water endotoxin level was 1.06 EU/ml. Sample port 5, outlet water endotoxin level was 5.36 EU/ml. Sample port 6, outlet water endotoxin level was 3.54 EU/ml. Sample port 7, outlet water culture was > 200 CFU/ml, the endotoxin level was 4.27 EU/ml. Repeat samples drawn 6/19/12 revealed the Bicarb mixer 1, feed sample port water culture 54 CFU/ml. Distribution loop 1, return sample port water culture was > 200 CFU/ml. Ultrafilter 1, feed sample port water culture was > 200 CFU/ml, the endotoxin level was 0.96 EU/ml. Pre-disinfection samples drawn 6/25/12 revealed the Ultrafilter 1, feed sample port water culture was > 200 CFU/ml. Distribution loop 1, return sample port water culture was > 200 CFU/ml. The water holding tank and loop were disinfected on 6/27/12.

There was no documentation the Medical Director had reviewed and monitored the elevated water culture and endotoxin levels during the month of June 2012.

7/2012 - Post-disinfection samples drawn 7/6/12 revealed the Ultrafilter 1, feed sample port water culture was 128 CFU/ml. A sample drawn 7/10/12 revealed the Distribution loop 1, return sample port water culture was > 200 CFU/ml. Ultrafilter 1, feed sample port water culture was >

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V 179	Continued From page 18 200 CFU/ml. Bicarb mixer 1, feed sample port water culture was > 200 CFU/ml. Pre-disinfection samples drawn 7/15/12 revealed the Distribution Loop 1, return sample port water culture was > 200 CFU/ml. Ultrafilter 1, feed sample port water culture was > 200 CFU/ml. Acid Mixer 1, feed sample port water culture was > 200 CFU/ml. The water holding tank and loop were disinfected 7/15/12. A sample drawn 7/31/12 revealed the Distribution loop 1, return sample port water culture was > 200 CFU/ml. Ultrafilter 1, feed sample port water culture was 158 CFU/ml. Acid Mixer 1, feed sample port water culture was 180 CFU/ml. There was no documentation the Medical Director had reviewed and monitored the elevated water culture levels during the month of July 2012. 8/2012 - Pre-disinfection samples drawn 8/5/12 revealed the Ultrafilter 1, feed sample port water culture was > 200 CFU/ml. Distribution Loop 1, return sample port water culture was > 200 CFU/ml. The water holding tank and loop were disinfected 8/5/12. Pre-disinfection sample drawn 8/17/12 revealed the Ultrafilter 1, feed sample port water culture was > 200 CFU. The 500 gallon holding tank was replaced with a 250 gallon unit on 8/18/12. The tank and the loop were disinfected 8/19/12. Post-disinfection sample drawn 8/29/12 revealed the Ultrafilter 1, feed sample port water culture was 150 CFU/ml. There was no documentation the Medical Director had reviewed and monitored the elevated water culture levels during the month of August 2012. 9/2012 - Water samples drawn 9/6/12 revealed	V 179		

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V 179	Continued From page 19 the Distribution Loop 1, return sample port water culture was 132 CFU/ml. Ultrafilter 1, feed sample port water culture was > 200 CFU/ml. Water samples drawn 9/11/12 revealed the Ultrafeed 1, feed sample port water culture was > 200 CFU/ml. Storage tank 1, feed sample port water culture was 102 CFU/ml. Distribution loop 1, return sample port water culture was 184 CFU/ml. Pre-disinfection samples drawn 9/16/12 revealed the Ultrafilter 1, outlet sample port water culture was 180 CFU/ml. Ultrafilter 1, feed sample port water culture was > 200 CFU/ml. Distribution loop 1, return sample port water culture was > 200 CFU/ml. The hemodialysis RO and loop were disinfected 9/16/12. Pre-disinfection samples drawn 9/26/12 revealed the Ultrafilter 1, feed sample port water culture was 74 CFU/ml. The water holding tank and loop were disinfected 9/26/12. There was no documentation the Medical Director had reviewed and monitored the elevated water culture levels during the month of September 2012. 10/2012 - A water sample drawn 10/3/12 revealed the Ultrafilter 1, feed sample port water culture was 140 CFU/ml. The water treatment system was disinfected 10/10/12. Post-disinfection samples drawn 10/12/12 revealed the Ultrafilter 1, feed sample port water culture was 126 CFU. There was no documentation the Medical Director had reviewed and monitored the the elevated water culture levels for 10/2/11 and 10/12/12. During an interview in the conference room on	V 179		

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V 179	Continued From page 20 10/16/12 at 4:35 PM, the Technical Supervisor verified there had been water problems since February 2012. During an interview in the conference room on 10/16/12 at 4:55 PM when the Director of Operations was asked if she felt the patients had been at risk for any problems related to the water, she stated, "...we looked at infections... looked at validations... did seek and try to resolve it... [have] piece of mind in that dialysate is clear..." During an interview in the water room on 10/18/12 at 10:37 AM, the Technical Operations Director stated the next step was to replace the loop. During a telephone interview from the conference room on 10/18/12 at 3:00 PM, the surveyor asked the Medical Director if he was aware of the issues with the water culture and endotoxin levels being out-of-range for the past year. The Medical Director stated he was aware. The Medical Director failed to ensure the development and implementation of an action plan to determine the root cause of the elevated bacteria and endotoxins in the water used to prepare dialysate, and to ensure the elevated levels were treated in a manner to ensure patient safety for the months of 4/2011, 5/2011, 6/2011, 7/2011, 8/2011, 9/2011, 10/2011, 11/2011, 12/2011, 1/2012, 2/2012, 3/2012, 4/2012, 5/2012, 6/2012, 7/2012, 8/2012, 9/2012, and 10/2012 resulting in IMMEDIATE JEOPARDY. Review of the facility hemodialysis schedules and treatment records revealed patients continued to dialyze during the months of 4/2011 - 10/2012 when the water cultures and/or endotoxins were elevated	V 179		

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V 179	Continued From page 21 demonstrating the IMMEDIATE JEOPARDY situation continues.	V 179		
V 190	494.40(a) SOFTENERS-AUTO REGENERATE/TIMERS/SALT LVL 5.2.4 Softeners: auto regen/timers/salt/salt level Prior to exhaustion, softeners should be restored; that is, new exchangeable sodium ions are placed on the resin by a process known as "regeneration," which involves exposure of the resin bed to a saturated sodium chloride solution. 5.2.4 Softeners Refer to RD62:2001, 4.3.10 Automatically regenerated water softeners: Automatically regenerated water softeners shall be fitted with a mechanism to prevent water containing the high concentrations of sodium chloride used during regeneration from entering the product water line during regeneration. The face of the timers used to control the regeneration cycle should be visible to the user. 6.2.4 Softeners Timers should be checked at the beginning of each day and should be interlocked with the RO system so that the RO is stopped when a softener regeneration cycle is initiated. The softener brine tank should be monitored daily to ensure that a saturated salt solution exists in the brine tank. Salt pellets should fill at least half the tank. Salt designated as rock salt should not be used for softener regeneration since it is not refined and typically contains sediments and other impurities that may damage O-rings and pistons and clog orifices in the softener control head.	V 190		

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This STANDARD is not met as evidenced by:
Based on policy review, observation and interview, the facility failed to follow their policy for monitoring salt pellets in the brine tank for 3 of 4 (10/15/12, 10/16/12, and 10/18/12) observation days.

The findings included:

1. Review of the facility's "Water Treatment Equipment" policy revealed, "...The top level of the salt pellets in the brine tank must be maintained above the level of the brine solution in the tank..."

2. Observation in the water room on 10/15/12 at 4:25 PM revealed the salt pellets inside the brine tank were below the solution level.

3. Observation in the water room on 10/16/12 at 4:15 PM revealed the salt pellets inside the brine tank were below the solution level.

4. Observation in the water room on 10/18/12 at 10:19 AM revealed the Technical Operations Manager opened the brine tank lid and observed salt pellets piled on one side allowing water to be visible.

5. During an interview in the water room on 10/15/12 at 4:30 PM, the Biomed Technician stated, "...that is supposed to be checked daily by whoever checks the chlorine at the beginning of the day..."

6. During an interview in the water room on

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V 190	Continued From page 23 10/16/12 at 12:00 PM, the Technical Supervisor stated, "...the system regenerates on non nocturnal nights and the next morning would fill with salt if needed..." 7. During an interview in the water room on 10/16/12 at 12:00 PM, the Biomed Technician stated, "...there should be more salt. The person who checked the tank this morning didn't add it..." 8. During an interview in the water room on 10/18/12 at 10:19 AM the Technical Operations Manager was asked by the surveyor if the salt was leveled out would it be above the level of the water? He stated, "Needs more salt."	V 190		
V 274	494.40(c) H20 TEST-DEVIATIONS REQUIRE RESPONSE Water testing results including, but not limited to, chemical, microbial, and endotoxin levels which meet AAMI action levels or deviate from the AAMI standards must be addressed with a corrective action plan that ensures patient safety. This STANDARD is not met as evidenced by: Based on facility policy review, culture and endotoxin reports, and facility Quality Assessment and Performance Improvement (QAI) Incenter Hemodialysis Meeting Minutes, the facility failed to develop and implement a corrective action plan that ensured patient safety when bacterial and endotoxin results identified recurrent levels outside the allowable limits and action levels in the water treatment system used to prepare water for dialysis for 19 of 19 (4/11, 5/11, 6/11, 7/11, 8/11, 9/11, 10/11, 11/11, 12/11, 1/12, 2/12, 3/12, 4/12, 5/12, 6/12, 7/12, 8/12, 9/12 and 10/12) months reviewed.	V 274		

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V 274	Continued From page 24 Failure of the Quality Assessment and Performance Improvement committee to develop and implement a corrective action plan for the recurrent elevated microbial levels resulted in a SERIOUS AND IMMEDIATE THREAT to all patients receiving hemodialysis and placed them at risk for complications including serious infection and death. The findings included: Review of the facility "Quality Assessment and Performance Improvement Program (QAPI)" policy revealed, "The Quality Assessment and Performance Improvement (QAI) Program encompasses all aspects of patients care ... is responsible for monitoring, problem solving, and reporting ... The QAI Program is designed and implemented to objectively, systematically, and comprehensively monitor, evaluate, and improve the quality and appropriateness of patient care and services by identifying opportunities and resolving identified problems ... The facility QAI Committee establishes priorities, develops and implements improvement projects based on established priorities and monitors these projects for effectiveness ... The Technical Services Representative is responsible for: Identification of improvement opportunities; Reporting on technical related issues, including water and dialysate ... The facility must take immediate, appropriate actions to address any serious threats and ensure patient safety. Examples of urgent priorities which could pose a threat to the health and safety of our patients and require immediate correction include ... Dangerous levels of contaminant in product water ... Elements to be	V 274		

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V 274	Continued From page 25 reviewed in the QAI meeting include ... Technical Operations, including water and dialysate quality and safety ..." Review of the facility's policy, "Microbiological Monitoring of Water Used for Dialysis Purposes", documented, "...Water cultures will be monitored using the following action level and allowable limits; Bacteria RO or DI Product - Action level 20 CFU/ml and Allowable limit 50 CFU/ml. Bacteria RO Distribution - Action level 50 CFU/ml and Allowable limit 200 CFU/ml. Endotoxin RO or DI Product Action level .25 EU/ml and Allowable level 1 EU/ml. Endotoxin RO Distribution - Action level 1 EU/ml and Allowable limit 2 EU/ml... Test results exceeding the Action Level or allowable limits - Promptly (within 48 hours) notify the Medical Director...Discuss with Medical Director, the creation of an action plan when test results indicate that the "Allowable limits" have been exceeded..." Review of the bacterial cultures and endotoxin testing results for the water treatment system during the months of 4/11, 5/11, 6/11, 7/11, 8/11, 9/11, 10/11, 11/11, 12/11, 1/12, 2/12, 3/12, 4/12, 5/12, 6/12, 7/12, 8/12, 9/12, and 10/12 documented culture and/or endotoxin levels outside the allowable or action levels. Review of the QAI meeting minutes dated 7/11, 8/11, 9/11, 10/11, 11/11, 12/11, 1/12, 2/12, 3/12, 4/12, 5/12, 6/12, 7/12 and 9/12 revealed no documentation the elevated water cultures and endotoxin levels were tracked and trended to determine a root cause for the continued elevated water cultures and endotoxin levels. There was no documentation an action plan was developed	V 274		

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V 274	Continued From page 26 and implemented to ensure the water cultures and endotoxins were maintained within the acceptable parameters. Attached to the QAPI meeting minutes were communication summaries used by the technicians to show the summary of water cultures and endotoxin levels elevated outside of the allowable limits. Under the section of the QAPI meeting minutes titled, "Water/Dialysate Quality Monitoring: Microbiology and Water Chemical Analysis" in the area stating "Is disinfection required more than monthly...", the answer was marked "No"; the area titled "Improvement Area" was marked "No."	V 274		
V 400	494.60 CFC-PHYSICAL ENVIRONMENT This CONDITION is not met as evidenced by: Based on facility policy review, medical record review, observation and interview, the facility failed to maintain visibility of vascular access sites and line connections at all times. The facility's failure to maintain access and line visibility provided an opportunity for a disconnected line to be undetected leading to excessive blood loss for Pt #7 and resulting in a SERIOUS AND IMMEDIATE THREAT to the health and safety of Pt #7 and for all patients receiving hemodialysis at the facility and placed them at risk for serious complications including death. The findings included:	V 400		

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V 400	Continued From page 27 1. The facility failed to maintain visibility of vascular access sites and bloodline connectors during hemodialysis treatments resulting in Pt #7 experiencing excessive blood loss due to a disconnected access line. Refer to V 407.	V 400		
V 407	494.60(c)(4) PE-HD PTS IN VIEW DURING TREATMENTS Patients must be in view of staff during hemodialysis treatment to ensure patient safety, (video surveillance will not meet this requirement). This STANDARD is not met as evidenced by: Based on facility policy review, medical record review, observation and interview, the facility failed to maintain visibility of hemodialysis access sites and line connections during treatment for 2 of 17 (Pt #7 and 14) sampled patients and 4 (RP #1, 2, 3 and 4) Random Patients. The facility's failure to adequately visualize and monitor Pt #7's vascular access during treatment on 9/18/12 resulted in excessive blood loss of approximately 1500 ml. The facility's failure to adequately visualize and monitor hemodialysis access sites and bloodlines resulted in a SERIOUS AND IMMEDIATE THREAT to the health and safety of Patient #7 and all patients receiving hemodialysis at the facility placing them at risk for serious complications including death. Continued disregard for maintaining visibility and monitoring vascular access sites demonstrates the IMMEDIATE JEOPARDY continues. The findings included:	V 407		

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V 407	Continued From page 28 1. Review of the facility's policy and procedure, "Patient Monitoring During Patient Treatment" documented, "POLICY: Monitor the patient at the initiation of treatment and every 30 minutes, or more frequently as necessary... Vital Signs/Mental Status: Vital signs will be monitored at the initiation of dialysis and every 30 minutes, or more frequently, as needed.... Access: Observe and document at the initiation of dialysis and at every safety check that all connections are secure and visible... Ensure access remains uncovered throughout the treatment. Documentation: Documentation of monitoring will be completed on the treatment record." Review of the facility policy, "Patient Safety Checks" documented, "Purpose: The purpose of this policy is to provide guidance on safety checks to prevent, detect and treat complications. Responsibility: direct Patient Care Staff (based on job description, licensure, certification, Federal/State regulations). Policy: Safety checks will be performed pre treatment and every 30 minutes or more frequently as needed once the treatment has begun. CAUTION: VASCULAR ACCESS, NEEDLE/CATHETER INSERTIONS SITES, BLOODLINE CONNECTIONS AND PATIENT'S FACES SHOULD BE VISIBLE AT ALL TIMES." 2. Medical record review for Pt #7 revealed an admission date of 3/1/06 with diagnosis of End Stage Renal Disease. Her pre treatment vital signs at 9:32 AM on 9/18/12 were blood pressure 117/78 and pulse 121 R (regular). Review of the Treatment Sheet dated 9/18/12 revealed the patient's treatment was started at 9:43 AM and	V 407		

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the Pre-Treatment Nursing Assessment was completed at 9:46 AM (after the start of the treatment). The RN Evaluation documented no unusual findings.
There was no documentation of vital signs, access checks or safety checks from 9:43 AM until 11:12 AM. At 11:12 AM, the PCT documented the patient's vital signs (BP-100/68 P-117) and that the patient was alert and resting comfortably. At 12:07 PM, vital signs were documented (BP-94/70 P-114) by the PCT and that the patient was, "alert, denies complaints, resting comfortably."

The Post Dialysis Vitals and Evaluation section of the Treatment Record documented, "Post vitals unable to complete-patient emergency." The Nursing Evaluation documented, "9/18/12 15:57 (3:57 PM) RN Evaluation-No unusual findings noted. Notes: at aprox 1210 pt became non responsive O2 applied, 911 called, 2000 ml of saline given and 2 cordial thumps administered, 20 compressions given, became responsive, was alert and responsive at time of departure. Aprox 1500 ml blood loss." Her post dialysis vital signs at 12:20 PM documented a blood pressure of 109/57 and pulse 144 IR (irregular).

Review of the facility's event form dated 9/26/12 and completed by the Director of Operations documented, "Brief Summary of Incident: On September 18, 2012 [Pt #7] was receiving her dialysis treatment. She told the patient care tech that she was feeling short of breath and asked if he would put her chair back (head down). The patient became unresponsive. CPR was initiated, Normal Saline was administered as her blood was rinsed back and 911 called. During initiation

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of CPR it was noted that the venous needle and line had become separated and the patient had experienced blood loss. The lines were reconnected and CPR, rinse back with normal saline administration continued. Patient opened her eyes and was alert and oriented. Patient was sent to the emergency room by ambulance."

Review of the hospital's consultation report dated 9/18/12 documented, "A stat hemoglobin [the oxygen-carrying pigment of the red blood cell] was 7.4 with hematocrit [the volume of packed red cells in a blood specimen] of 22.8. The most previous hematocrit that I have available from last week was 36."

Review of the patient's lab reports revealed on 8/21/12 HCT was 39.2 [normal range 37-47]. On 8/28/12 her Hgb was 12.3 [normal range 12-16] and on 9/4/12 her Hgb was 12.1. On 9/18/12 at 9:40 AM prior to needle dislodgement, her Hgb was 12.5 and on 9/27/12 her Hgb was 10.3.

Review of the IDT evaluation dated 2/24/12 revealed no documentation of concerns with the patient covering her access site. Review of the Comprehensive Social Worker Assessment dated 8/7/12 revealed no documentation that the patient was non-compliant with keeping her access uncovered.

Review of the Plan of Care signed by the IDT on 2/24/12 revealed no documentation that the patient was non-compliant with keeping her access uncovered. Review of the 6 Month Patient Plan of Care Updated dated 8/10/12 revealed no documentation to address concerns with the patient keeping her access covered

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during treatments. Review of the Monthly Patient Plan of Care dated 9/14/12 revealed no documentation to address concerns with the patient keeping her access covered during treatments.

During a telephone interview on 10/23/12 at 2:10 PM, PCT #5 stated, "I was doing blood pressures on that section of patients. I had just checked her [Pt #7]. She coughed a funny cough. She had been coughing because I had given her an emesis basin earlier because she was spitting up. When she coughed funny I called for the nurse. She came over and saw that [patient] was gasping for air. She reclined her in the chair all the way. The chairs go into Trendelenburg [position where the patient is flat on a table or bed, with head positioned 30-40 degrees downward] position and started CPR. I started rinse back, and another nurse came over to help. We didn't notice her bleeding. [Patient] always kept her access covered. She said she was cold."

During a telephone interview with the Medical Director on 10/18/12 at 3:00 PM, the Medical Director stated he was aware of the blood loss incident with this patient and an investigation was conducted that revealed the facility did not follow their protocol for using the correct lines. A manual line was used instead of a twister access line.

Failure of the facility to maintain visibility of the hemodialysis access site and monitor for bleeding for at the access site resulted in loss of approximately 1500 cc of blood for Pt. #7.

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V 407	Continued From page 32 3. Observations on 10/15/12 beginning at 1:45 PM revealed Pt #14 receiving hemodialysis with his access covered by the sleeve of his shirt. 4. Observations on 10/15/12 beginning at 1:52 PM revealed RP #1 was covered with a blanket from the knees to shoulders. The patient was continuously observed from 1:52 PM to 3:10 PM and the staff did not uncover or assess the patient's access site or line connections. 5. Observations on 10/15/12 beginning at 2:17 PM revealed RP #2 notified the PCT that she was cramping. The nurse was observed to give the patient a normal saline bolus. During this time the patient's access site was covered with a quilt. Neither the nurse nor the PCT uncovered the access site. 6. Observations on 10/17/12 beginning at 8:20 AM revealed RP #3 and RP #4 were receiving hemodialysis treatment with their access sites covered by a blanket.	V 407		
V 500	494.80 CFC-PATIENT ASSESSMENT This CONDITION is not met as evidenced by: Based on facility policy review, medical record review and interview, the facility failed to follow policies for monitoring blood pressures and administration of normal saline for cramping. The findings included: 1. The facility failed to follow its policies for hypertension and hypotension parameters for treatment and normal saline administration for	V 500		

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V 500	Continued From page 33 cramping. Refer to V 504	V 500		
V 504	494.80(a)(2) PA-ASSESS B/P, FLUID MANAGEMENT NEEDS The patient's comprehensive assessment must include, but is not limited to, the following: Blood pressure, and fluid management needs. This STANDARD is not met as evidenced by: Based on policy review, medical record review and interview, the facility failed to follow policies for the treatment of blood pressures out of parameters and treatment of cramping for 7 of 17 (Pt #1, 4, 6, 7, 8, 12 and 17) sampled patients. The findings included: 1. Review of the facility's "Blood Pressure Management Treatment Parameters" policy revealed, "...Hypertension SBP > 190 and/or DBP > 110...Intradialytic Hypertension...If asymptomatic administer 0.1 mg Clonidine per MD order...Check BP in 1 hour. If BP decreasing continue to monitor. If BP still elevated above parameters administer second dose of Clonidine 0.1 mg PO ...Check BP again in 1 hour. If BP still elevated 1 hour after second dose notify MD for further orders...Post Treatment...If asymptomatic administer 0.1 mg Clonidine per MD order. Check BP in 1/2 hour. If BP decreasing patient may be discharged. If BP is still above parameters notify MD for further orders...Hypotension SBP <100...Pre Treatment...If asymptomatic initiate treatment and	V 504		

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V 504	Continued From page 34 administer 200 ml Normal Saline in addition to normal prime...If BP decreasing notify MD...Post Treatment...administer additional 200 ml NS...Check BP in 5 minutes...If BP increasing patient may be discharged..." 2. Review of the facility policy, "Treatment of Muscle Cramping" revealed, "Follow the steps below to treat muscle cramps during the hemodialysis treatment...Reduce target goal, or turn UF button "off". 2. Take blood pressure, as muscle cramps commonly occur in conjunction with hypotension. 3. If blood pressure is low, give 100 ml. normal saline per procedure...to replace fluid and sodium to the bloodstream and tissues...4. Repeat bolus of normal saline in 100 ml. increments, if necessary for hypotension. Maximum of 500 ml. normal saline..." 3. Medical record review for Pt #1 revealed the following elevated blood pressure readings which were not treated: 8/29/12 - BP's of 210/72 at 11:33 AM, 192/79 at 12:03 PM, 168/112 at 1:13 PM. 8/31/12 - BP's of 200/79 at 11:11 AM, 197/80 at 12:05 PM, 204/78 at 12:46, 193/76 at 1:31 PM, 166/144 at 1:55 PM. 9/3/12 - BP's of 198/87 at 11:33 AM, 196/80 at 12:37 PM, 202/79 at 1:40 PM and 193/85 at 2:47 PM. 9/12/12 - BP's of 204/77 at 11:10 AM, 205/83 at 11:39 AM, 196/81 at 12:40 PM, 194/72 at 1:03 PM, 196/77 at 2:02 PM. 9/21/12 - BP's of 197/98 at 12:11 PM, 204/82 at 2:00 PM and 211/93 at 2:30 PM. 9/24/12 - BP's of 208/91 at 11:22 AM and 198/85 at 12:35 PM. 9/26/12 - BP's of 217/91 at 11:06 AM, 211/91 at	V 504		

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V 504	Continued From page 35 11:07, 210/96 at 11:34 AM and 197/88 at 12:11 PM. 4. Medical record review for Pt #4 revealed the following elevated blood pressure reading which was not treated: 9/11/12 - BP of 166/112 on the post vital signs evaluation. 5. Medical record review for Pt #6 revealed the following elevated blood pressure readings which were not treated: 8/29/12 - BP of 225/107 at 12:06 PM. 9/12/12 - BP of 173/138 at 2:28 PM. 6. Medical record review for Patient #7 documented on the Hemodialysis Flowsheet dated 8/7/12, "11:50 AM ...pt complained of mild cramping, goal reduce and rn is aware. 12:11 PM blood pressure 58/43 Patient alert; pt not feeling well 200 ns giving reduced goal to 3000. 12:15 PM Patient alert; 200 ns giving will continue to monitor." Review of the LPN's documentation on the Post Dialysis Vitals and Evaluation revealed at 1:22 PM the patient's blood pressure was 80/57 and her heart rate was 113. The LPN documented the patient was discharged home at 1:39 PM. At 2:55 PM on the Post Assessment Nursing Evaluation, the RN documented, "Post assessment done, pt sent to [name of local hospital] for low bp and increased hr per [name of nurse practioner]. [Patients doctor name] aware." Further medical record review for Pt #7 revealed the following decreased blood pressure readings which were not treated: 8/28/12 -BP's of 76/54 at 12:07 PM, 79/55 at 12:32 PM, 78/55 at 1:04 PM, and 82/51 at 1:26	V 504		

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V 504	Continued From page 36 PM. 9/1/12 - BP's of 73/56 at 12:01 PM, and 73/51 at 12:39 PM. 9/4/12 - BP's of 76/54 at 10:37 AM, 70/50 at 10:52 AM, 79/56 at 11:06 AM, 76/57 at 11:18 AM, 74/58 at 11:36 AM, 80/58 at 12:11 PM, and 77/55 at 12:35 PM. 8. During an interview in the Biomed room on 10/8/12 at 3:43 PM, the DOO stated, "...we recognized we have blood pressure issues...got special permission from technical to see where we could post parameters [on the hemodialysis machines]..." 9. Medical record review for Patient #8 documented on the Hemodialysis Flowsheet dated 6/1/12, "18:05 [6:05 PM] c/o cramping. uf goal is cut back to min. 300 cc ns is given by RN's advice continue to monitor" There was no documentation that the patients blood pressure was taken and addressed. On 6/6/12 at 5:32 PM, "pt states cramping uf goal was reduced to minimum team leader gave 200 ml of ns bp stable." 10. Medical record review for Patient #12 documented on the Hemodialysis Flowsheet dated 2/2/12, "pt c/o cramping in hands goal decreased to 3800 150 ml NS given bp stable. (b/p 139/45)". On 2/11/12 at 12:32 PM the Hemodialysis Flowsheet documented, "patient b/p is low (81/38) nurse notified patient was given 150 cc of saline per nurse patient uf goal was reduced from 3500 to 300 per nurse. On 2/21/12 the Hemodialysis Flowsheet documented, "11:47 AM c/o cramping gave 200 ml ns and decreased goal to 3690. 11:50 AM pt c/o cramping no	V 504		

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V 504	Continued From page 37 easing gave 200 ml ns pt stated subsided." 11. Medical record review for Patient #17 documented on the Hemodialysis Flowsheet dated 9/28/12, "Multidisciplinary Notes: 7:40 b/p stable but pt cramping in right calf, ankle and foot. 400 cc ns given without relief, will continue to monitor." The patient's treatment ended at 9:57 AM and there was no other documentation to address the patient cramping. The facility failed to adhere to its policies and procedures for hypertension, hypotension, and muscel cramping.	V 504		
V 540	494.90 CFC-PATIENT PLAN OF CARE This CONDITION is not met as evidenced by: Based on facility policy review, medical record review and interview, the facility failed to develop measurable timetables, monitor patients pre/during/post dialysis, obtain patients input in POC, failed to implement a POC within timeframe after admission and failed to revise the POC to address patients non compliance with keeping accesses visible during treatments. The facility's failure to address and to revise the POC to include interventions for vascular access visibility and the failure to adhere to its own policies for patient monitoring resulted in SERIOUS AND IMMEDIATE THREAT to the health and safety of Patient #7 and all patients receiving hemodialysis at the facility and placed them at risk for potential death due to excessive blood loss.	V 540		

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V 540	Continued From page 38 The findings included: 1. The facility failed to develop measurable timetables for the POC. Refer to V 541. 2. The facility failed to include interventions for vascular access visibility in the POC and adequately monitor patients during dialysis, complete pre and post assessments and respond to hypertension/hypotension during treatments. Refer to V 543. 3. The facility failed to document the patients participation in the POC. Refer to V 556. 4. The facility failed to implement a POC within 30 days or 13 treatments after admission. Refer to V 557. 5. The facility failed to revise the POC to address patients non compliance with keeping accesses uncovered. Refer to V 559	V 540		
V 541	494.90 POC-GOALS=COMMUNITY-BASED STANDARDS The interdisciplinary team as defined at §494.80 must develop and implement a written, individualized comprehensive plan of care that specifies the services necessary to address the patient's needs, as identified by the comprehensive assessment and changes in the patient's condition, and must include measurable and expected outcomes and estimated timetables to achieve these outcomes. The outcomes	V 541		

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V 541	Continued From page 39 specified in the patient plan of care must be consistent with current evidence-based professionally-accepted clinical practice standards. This STANDARD is not met as evidenced by: Based on medical record review and interview, the facility failed to develop a POC with measurable timetables for 1 of 17 (Pt #17) sampled patients. The findings included: Medical record review for Pt #17 documented a 90 day POC dated 9/28/12 by the IDT. Review of the care plan problems for Blood Pressure & Fluid Management, Anemia Management, and Dialysis Access revealed no documentation of measurable time tables to meet goals. During an interview on 10/17/12 at 5:05 PM, the Director of Operations verified that the POC did not have measurable time tables.	V 541		
V 543	494.90(a)(1) POC-MANAGE VOLUME STATUS The plan of care must address, but not be limited to, the following: (1) Dose of dialysis. The interdisciplinary team must provide the necessary care and services to manage the patient's volume status; This STANDARD is not met as evidenced by: Based on facility policy review, medical record review and interview, the facility failed to develop a POC that was individualized to include interventions to ensure vascular access sites remained visible, failed to ensure patients were	V 543		

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adequately monitored during dialysis, and failed to ensure assessments were completed before and/or after dialysis for 13 of 17 (Patients #1, 2, 3, 4, 6, 7, 8, 9, 11, 13, 14, 15 and 17) sampled patients.

The facility's failure to develop an individualized POC that included interventions to ensure vascular accesses were uncovered and visible throughout the hemodialysis treatment and monitored per policy resulted in a SERIOUS AND IMMEDIATE THREAT to the health and safety of Patient #7 when she had excessive blood loss. This resulted in a SERIOUS AND IMMEDIATE THREAT to the health and safety of all patients receiving hemodilaysis at the facility and placed them at risk for potential death due to excessive blood loss.

The findings included:

1. Review of the facility's "Comprehensive Interdisciplinary Assessment and Plan of Care" policy revealed, "...The patient's individualized comprehensive Plan of Care must include, but limited to the following: Dose of Dialysis... Provide necessary care and services to manage the patient's volume status... Vascular Access... Provide vascular access monitoring... Psychosocial Status... Provide necessary monitoring and social work interventions, including counseling services and appropriate referrals... Patient Education and Training... Include education and training for patients and family members or caregivers as applicable.... Updates to Plan... The Assessment/Update section of the Plan of Care should be updated monthly for patients identified as stable, but that

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are not meeting the expected goal within the established timeframe. If the patient is stable, but is NOT meeting the Plan of Care goals in specific areas, but is still within the established timeframe, then those areas should be reviewed and the Plan of Care revised, or changes documented elsewhere in the medical record, such as in the progress notes or attending physicians extender orders... Plan of Care discussions may be scheduled with the interdisciplinary team to review the Plan of Care and revise as indicated..."

2. Review of the facility's "Patient Safety Checks" policy revealed, "... The purpose of this policy is to provide guidance on safety checks to prevent, detect and treat complications... Safety checks will be performed pre treatment and every 30 minutes or more frequently as needed once the treatment has begun. CUATION: VASCULAR ACCESS, NEEDLE/CATHETER INSERTION SITES, BLOODLINE CONNECTIONS AND PATIENT'S FACES SHOULD BE VISIBLE AT ALL TIMES..."

3. Review of the facility's "Patient Monitoring During Patient Treatment" policy revealed, "... The purpose of this policy is to provide direction for monitoring dialysis patients during treatment to ensure patient safety... Monitor the patient at the initiation of treatment and every 30 minutes, or more frequently as necessary... Vital signs will be monitored at the initiation of dialysis and every 30 minutes, or more frequently as needed. Observe for changes in the patient's respirations, heart rate and blood pressure. Verify and react to unusual findings such as atypical blood pressure readings. Access: Observe and document at the initiation of dialysis and at every safety check that

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V 543	Continued From page 42 all connections are secure and visible... Ensure that bloodlines are secured to the patients... Ensure access remains uncovered throughout the treatment; Observe and ensure: Tape is secure; Needles are intact; No bleeding or infiltration is noted... Documentation of monitoring will be completed on the treatment record. Appropriate interventions in response to changes in vital signs, treatment parameters, or machine adjustments shall be documented in the treatment record..." 4. Review of the facility's "Patient Evaluation Pre Dialysis Treatment" policy revealed, "...The purpose of this policy is to provide guidance on evaluating the patient prior to initiating the dialysis treatment... [name of company] patient care staff will complete a pre dialysis evaluation prior to initiation of patient treatment... Performing an evaluation pre dialysis will assist the Clinician in identifying potential problems that may arise during dialysis treatment... Patient assessment is a nursing responsibility and cannot be delegated to unlicensed patient care staff... The assessment must be documented in the patient's medical record... Facilities in states that require nursing assessments for all patients should continue to perform and document the assessments as required..." 5. Review of the facility's "Patient Evaluation Post Dialysis Treatment" policy documented, "...The purpose of this policy is to provide guidance on evaluating the patient after the dialysis treatment... [name of company] patient care staff will complete an evaluation post dialysis treatment on every patient... Patient assessment is a nursing responsibility and cannot be	V 543		

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V 543	Continued From page 43 delegated to unlicensed patient care staff... The assessment must be documented in the patient's medical record... Facilities in states that require nursing assessments for all patients should continue to perform and document the assessments as required..." 6. Review of the facility's "Monitoring the In-center Nocturnal Dialysis Patient" policy revealed, "...Nocturnal hemodialysis patients will have blood pressure and pulse obtained and documented at a frequency of not less than every two hours...the dialysis extracorporeal circuit and dialysis machine safety checks will be monitored and documented every 30 minutes during the patient's treatment..." 7. Medical record review for Pt #7 revealed the treatment flow sheet documented the following on 8/28/12: treatment was initiated at 10:04 AM, the RN preassessment was done at 11:15 AM and VS were not documented every 30 minutes. On 9/1/12, 9/4/12 and 9/6/12 VS and safety checks were not documented every 30 minutes. On 9/11/12 treatment was initiated at 9:34 AM. Review of the flowsheet revealed a physician's order to increase blood pressure checks to every 15 minutes. VS were not documented every 15 minutes. On 9/18/12 treatment was initiated at 9:43 AM. The RN preassessment was not done until 9:46 AM. Review of the facility's event form dated 9/26/12 and completed by the Director of Operations documented, "Brief Summary of Incident: On September 18, 2012 [Pt #7] was receiving her dialysis treatment. She told the patient care tech	V 543		

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that she was feeling short of breath and asked if he would put her chair back (head down). The patient became unresponsive. CPR was initiated, Normal Saline was administered as her blood was rinsed back and 911 called. During initiation of CPR it was noted that the venous needle and line had become separated and the patient had experienced blood loss. The lines were reconnected and CPR, rinse back with normal saline administration continued. Patient opened her eyes and was alert and oriented. Patient was sent to the emergency room by ambulance."

Review of the IDT evaluation dated 2/24/12 revealed no documentation Pt #7 covered her access during the hemodialysis treatment. Review of the Comprehensive Social Worker Assessment dated 8/7/12 revealed no documentation Pt #7 covered her access during treatment.

Review of the Plan of Care dated 2/24/12, the 6 Month Patient Plan of Care updated 8/10/12, and the Monthly Patient Plan of Care dated 9/14/12 revealed no documentation by the IDT that Patient #7 kept her access covered during treatments.

During a telephone interview on 10/23/12 at 2:10 PM PCT #5 was asked about Pt #7's blood loss on 9/18/12. PCT #5 stated, "... We didn't notice her bleeding... [Pt #7] always kept her access covered. She said she was cold..."

The facility's failure to ensure visibility of the vascular access site and to monitor the access per policy and ensure the Plan of Care was individualized with interventions to keep vascular

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V 543	Continued From page 45 accesses uncovered during hemodialysis treatment resulted in SEVERE AND IMMEDIATE THREAT to the health and safety of Patient #7 and all patients receiving hemodialysis at the facility and placed Patient #7 at risk for potential death due to excessive blood loss. 8. Medical record review for Pt #1 revealed the 9/21/12 treatment flow sheet documented treatment was initiated at 11:30 AM. The RN preassessment was not done until 3:05 PM and VS were not documented every 30 minutes. 9. Medical record review for Pt #3 revealed the treatment flow sheets did not document VS every 30 minutes on 8/29/12, 9/7/12, 9/12/12, and 9/17/12. Rview of the treatment flowsheets did not documet safety checks every 30 minutes on 9/12/12 and 9/17/12. 10. Medical record review for Pt #4 revealed the treatment flow sheet dated 9/1/12 documented treatment was initiated at 9:45 AM. The RN preassessment was not done until 10:03 AM and VS were not documented every 30 minutes. On 9/6/12 treatment was initiated at 10:00 AM. The RN preassessment was not done until 10:14 AM and VS were not documented every 30 minutes. On 9/8/12 and 9/11/12 the patient's VS were not documented every 30 minutes. On 9/15/12 treatment was initiated at 10:21 AM. The RN preassessment was not done until 2:49 PM and VS were not documented every 30 minutes. On 9/20/12 treatment was initiated at 10:38 AM and the first VS were documented at 12:08 PM.	V 543		

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V 543	Continued From page 46 11. Medical record review for Pt #6 revealed the treatment flow sheets documented VS were not done every 30 minutes on 8/29/12, 9/12/12, 9/21/12, 9/24/12 and 9/26/12 and safety checks were not documented every 30 minutes on 8/29/12, 9/12/12, 9/21/12 and 9/24/12. On 9/12/12 treatment was initiated at 11:49 AM. the RN preassessment was documented at 8:37 PM. On 9/21/12 treatment was initiated at 10:51 AM, and there was no preassessment documented. 12. Medical record review for Pnt #8 revealed the treatment flow sheets did not document VS every 30 minutes on 6/1/12. 13. Medical record review for Pt #9 revealed the treatment flow sheets did not document VS evey 30 minutes on 1/20/12 and 1/30/12. 14. Medical record review for Pt #11 revealed the treatment flow sheets did not document VS evey 30 minutes on 7/3/12, 7/5/12 and 7/7/12. 15. Medical record for Pt #13 revealed the treatment flow sheet did not document VS every 30 minutes on 5/19/12. 16. Medical record review for Pt #14 revealed the treatment flow sheets did not document VS every 30 minutes on 9/14/12, 9/21/12 and 10/12/12. 17. Medical record review for Pt #15 revealed the treatment flow sheets did not document VS and safety checks every 30 minutes on 9/28/12 and 10/15/12. 18. Medical record review for Pt #17 revealed the	V 543		

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V 543	Continued From page 47 treatment flow sheets did not document VS every 30 minutes on 9/24/12, 9/26/12, 9/28/12, 10/1/12, 10/5/12 and 10/15/12 and safety checks were not documented every 30 minutes on 9/24/12. 19. Medical record review for Pt #2 revealed he received In-center nocturnal hemodialysis. The treatment flow sheets did not document VS every 2 hours on 8/19/12, 8/26/12, and 9/13/12. The treatment flowsheet did not document safety checks every 30 minutes 8/23/12, 8/26/12, 8/30/12, 9/2/12, 9/6/12, 9/13/12, 9/20/12 and 9/23/12. There was no RN documentation of a post assessment on 8/30/12 20. During an interview in the Biomed room on 10/8/12 at 2:15 PM, the Director of Operations stated, "...the system we now have takes the vital signs...they have to look at the blood pressure, acknowledge it before it crosses over..."	V 543		
V 547	494.90(a)(4) POC-MANAGE ANEMIA/H/H MEASURED Q MO The interdisciplinary team must provide the necessary care and services to achieve and sustain the clinically appropriate hemoglobin/hematocrit level. The patient's hemoglobin/hematocrit must be measured at least monthly. The dialysis facility must conduct an evaluation of the patient's anemia management needs. This STANDARD is not met as evidenced by: Based on policy review, medical record review and interview, the facility failed to ensure Heparin was administered as ordered by the physician for	V 547		

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V 547	Continued From page 48 2 of 17 (Pt #'s 3 and 15) sampled patients. The findings included: 1. Review of the facility's "Heparinization" policy revealed, "...Stopping the Heparin Pump...It is recommended the heparin pump be stopped: 30 minutes prior to the end of treatment in accordance with a physician order on patients dialyzing through a fistula or graft..." 2. Review of the facility's Physician Order Documentation" policy revealed, "...General Policy...Nurse practice acts require nurses to carry out treatment care, medication administration...based on physician orders..." 3. Medical record review for Pt #3 revealed the pt had an AV graft and a physician's order dated 9/20/11 for "...Heparin 1000U/H3.5 ...Every Sched TRMT..." Review of the treatment flowsheets for Pt #3 revealed the Heparin infusion was not discontinued within 30 minutes prior to the end of dialysis treatment as follows: 8/29/12 - treatment was completed at 10:05 AM and the Heparin infusion was completed at 10:05 AM. 9/3/12 - treatment was completed at 10:07 AM and the Heparin infusion was completed at 10:07 AM. 9/7/12 - treatment was completed at 10:12 AM and the Heparin infusion was completed at 10:12 AM. 9/12/12 - treatment was completed at 10:16 AM and the Heparin infusion was completed at 10:16 AM.	V 547		

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V 547	Continued From page 49 9/17/12 - treatment was completed at 10:07 AM and the Heparin infusion was completed at 10:31 AM. 9/19/12 - treatment was completed at 10:03 AM and the Heparin infusion was completed at 10:15 AM. 5. Review of the medical record for Pt #15 revealed a physician order dated 6/27/12 for "...Heparin...1,000 Units/ml Systemic- Infusion Rate 500 units per hour (1500 units during first three hours of treatment). Turn Heparin Pump Off 60 min prior to end of treatment..." Scheduled hours of treatment 4.0. Review of the treatment flowsheets for Pt #15 revealed the Heparin infusion was not discontinued within 60 minutes prior to the end of dialysis treatment and Pt #15 did not receive 1500 units of heparin as ordered: On 8/31/12 the treatment was completed at 2:42 PM, the Heparin infusion was completed at 2:42 PM with total Heparin infused 2,025.000. On 9/24/12, the flowsheet documented total Heparin infused was 2208.330. On 10/1/12 treatment was completed at 3:02 PM, the Heparin infusion was completed at 3:03 PM and the total Heparin infused was 2,033.330. On 10/15/12 treatment was completed at 2:06 PM, the Heparin infusion was completed at 6:10 PM and the total Heparin infused was 4,225.00. 8. During an interview in the biomed room on 10/8/12 at 3:20 PM, the DOO verified the Heparin infusions were not stopped 30 minutes prior to end of treatment as ordered and stated, "...My guess is she documented when she did the post assessment..."	V 547		

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V 556	494.90(b)(1) POC-COMPLETED/SIGNED BY IDT & PT The patient's plan of care must- (i) Be completed by the interdisciplinary team, including the patient if the patient desires; and (ii) Be signed by the team members, including the patient or the patient's designee; or, if the patient chooses not to sign the plan of care, this choice must be documented on the plan of care, along with the reason the signature was not provided. This STANDARD is not met as evidenced by: Based on policy review, record review and interview, the facility failed to include the patient in the plan of care for 2 of 17 (Pt's #3 and 17) sampled patients. The finding included: 1. Review of the facility's "Comprehensive Interdisciplinary Assessment and Plan of Care" policy revealed, "...Plan of Care Requirements...The Plan of Care must be signed by team members including the patient or patient designee. If the patient is unable or chooses not to sign the Plan of Care, this must be documented on the Plan of Care along with the reason the signature was not provided..." 2. Medical record review for Pt #3 documented a Plan of Care was developed by the IDT on 5/4/12. There was no indication by signature of the patient, that the patient had been involved in or approved the Plan of Care. There was no documentation why the patient had not been involved in or approved the Plan of Care.	V 556		

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V 556	Continued From page 51 3. Medical record review for Pt #17 documented the patient was admitted to the facility on 7/25/12 for ESRD. A plan of care was developed by the IDT on 9/28/12. As of 10/18/12, there was no indication by signature of the patient, that the patient had been involved in or approved her Plan of Care. There was no documentation why the patient had not been involved in or approved the Plan of Care. In an interview on 10/17/12 at 5:05 PM, the Director of Operations verified that the patient had not been involved in her care planning process.	V 556		
V 557	494.90(b)(2) POC-INITIAL IMPLEMENTED-30 DAYS/13 TX Implementation of the initial plan of care must begin within the latter of 30 calendar days after admission to the dialysis facility or 13 outpatient hemodialysis sessions beginning with the first outpatient dialysis session. This STANDARD is not met as evidenced by: Based on medical record review and interview, the facility failed to initiate a plan of care within 30 days or 13 treatments after admission for 1 of 17 (Pt #17) sampled patients. The findings included: Medical record review for Pt #17 documented she was admitted to the facility for chronic dialysis on 7/25/12. The first IDT Plan of Care was signed as a 90 day POC on 9/28/12.	V 557		

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V 557	Continued From page 52 During an interview in the conference room on 10/17/12 at 5:05 PM, the Director of Operations verified there was no POC within 30 days or 13 treatments after admission for chronic dialysis.	V 557		
V 559	494.90(b)(3) POC-OUTCOME NOT ACHIEVED-ADJUST POC If the expected outcome is not achieved, the interdisciplinary team must adjust the patient's plan of care to achieve the specified goals. When a patient is unable to achieve the desired outcomes, the team must- (i) Adjust the plan of care to reflect the patient's current condition; (ii) Document in the record the reasons why the patient was unable to achieve the goals; and (iii) Implement plan of care changes to address the issues identified in paragraph (b)(3)(ii) of this section. This STANDARD is not met as evidenced by: Based on medical record review and interview, the facility failed to adjust the POC to reflect the patient's current condition related to refusal to keep access visible for 1 of 17 (Pt #7) sampled patients. The facility's failure to assess and implement a POC to address access visibility resulted in SERIOUS AND IMMEDIATE THREAT to the health and safety of Pt #7 all patients receiving hemodialysis at the facility and placed them at risk for potential death due to excessive blood loss. The findings included:	V 559		

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V 559	Continued From page 53	V 559		

Medical record review for Pt #7 revealed the patient was admitted to the facility on 3/1/06 with diagnosis of End Stage Renal Disease.

Review of the IDT evaluation dated 2/24/12 revealed no documentation of concerns with the patient covering her access site. Review of the Comprehensive Social Worker Assessment dated 8/7/12 revealed no documentation that the patient was non-compliant with keeping her access uncovered.

Review of the Plan of Care signed by the IDT on 2/24/12 revealed no documentation that the patient was non-compliant with keeping her access uncovered. Review of the 6 Month Patient Plan of Care Updated 8/10/12 revealed no documentation to address concerns with the patient keeping her access covered during treatments. Review of the Monthly Patient Plan of Care dated 9/14/12 revealed no documentation of concerns with the patient keeping her access covered during treatments and no update to the POC since the occurrence on 9/18/12.

Review of the Post Dialysis Vitals and Evaluation section of the Treatment Record dated 9/18/12 documented, "Post vitals unable to complete-patient emergency."

Review of the facility's event form dated 9/26/12 and completed by the Director of Operations documented, "Brief Summary of Incident: On September 18, 2012 [Pt #7] was receiving her dialysis treatment. She told the patient care tech that she was feeling short of breath and asked if

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V 559	Continued From page 54 he would put her chair back (head down). The patient became unresponsive. CPR was initiated, Normal Saline was administered as her blood was rinsed back and 911 called. During initiation of CPR it was noted that the venous needle and line had become separated and the patient had experienced blood loss..." In a telephone interview on 10/23/12 at 2:10 PM, PCT #5 stated, "I was doing blood pressures on that section of patients. I had just checked her [Patient #7]. She coughed a funny cough. She had been coughing because I had given her an emesis basin earlier because she was spitting up. When she coughed funny I called for the nurse. She came over and saw that [patient] was gasping for air. She reclined her in the chair all the way. The chairs go into Trendelenburg [position where the patient is flat on a table of bed, with head positioned 30-40 degrees downward] position and started CPR. I started rinse back, and another nurse came over to help. We didn't notice her bleeding. [Patient] always kept her access covered. She said she was cold." The facility's failure to ensure a POCs was developed and implemented to address access visibility, even after Pt #7 experienced excessive blood loss, continued to place Pt #7 and all patients in a SERIOUS AND IMMEDIATE THREAT to the health and safety of all the patients receiving hemodialysis and placed them at risk for potential death.	V 559		
V 625	494.110 CFC-QAPI	V 625		

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V 625	Continued From page 55 This CONDITION is not met as evidenced by: Based on policy review, document review, record review and interview, the facility failed to ensure the QAPI committee provided effective quality assessment and performance activities that identified, prioritized and corrected major problems. The facility's failure to identify and address problems concerning vascular access visualization, monitoring of patient's during hemodialysis treatments and failure of the water treatment program to ensure testing results remained below allowable contamination levels resulted in SERIOUS AND IMMEDIATE THREAT to the health and safety of all the hemodialysis patients and placed them at risk for the potential of death and other complications from adverse events. The findings included: 1. The facility QAI program failed to trend results of testing for water used to prepare dialysate and develop a correction action plan effective in ensuring bacterial and endotoxin levels were maintained within acceptable parameters. Refer to V 627. 2. The facility QAI program failed to identify and take action to correct staff failure to follow facility policy and procedure for monitoring patients during hemodialysis treatments and patient failure to maintain vascular access site visibility during treatments. Refer to V-634.	V 625		
V 627	494.110(a)(1) QAPI-ONGOING;USES INDICATORS=IMPROVEMENT	V 627		

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V 627	Continued From page 56 The program must include, but not be limited to, an ongoing program that achieves measurable improvement in health outcomes and reduction of medical errors by using indicators or performance measures associated with improved health outcomes and with the identification and reduction of medical errors. This STANDARD is not met as evidenced by: Based on review of facility policy, water culture and endotoxin reports, water system disinfection logs, QAI meeting minutes and interview, the facility failed to ensure water testing results for recurrent elevated levels of bacterial growth and the presence of elevated levels of endotoxins were analyzed and addressed with a corrective action plan to ensure patient safety for 19 of 19 (4/2011-10/2012) months reviewed. The facility's failure to analyze the recurrent elevated levels of bacterial and endotoxins for a root cause and to implement corrective actions that eliminated the cause resulted in a SERIOUS AND IMMEDIATE THREAT to all patients receiving hemodialysis at the facility and placed them at risk for complications including serious infection and death. Facility hemodialysis schedules and treatment records indicate patient's continue to dialize during the months of 4/11 - 10/12 demonstrating the IMMEDIATE JEOPARDY continues. The findings included: Review of the facility's policy, "Microbiological Monitoring of Water Used for Dialysis Purposes", revealed, "....Water cultures will be monitored	V 627		

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V 627	Continued From page 57 using the following action level and allowable limits; Bacteria RO or DI Product - Action level 20 CFU/ml and Allowable limit 50 CFU/ml. Bacteria RO Distribution - Action level 50 CFU/ml and Allowable limit 200 CFU/ml. Endotoxin RO or DI Product Action level .25 EU/ml and Allowable level 1 EU/ml. Endotoxin RO Distribution - Action level 1 EU/ml and Allowable limit 2 EU/ml..." Review of the bacterial cultures and endotoxin testing results for the water treatment system for the months of 4/1011 - 10/2012 revealed culture and/or endotoxin levels outside the allowable or action level during each of the 19 months reviewed. Review of the QAI minutes from April 2011 through September 2012 revealed there was no documentation that the QAI committee trended or developed plans of action for the recurrent bacterial and endotoxins that were above the allowable or action levels. During an interview in the conference room on 10/16/12 at 4:35 PM, the Technical Supervisor verified he was aware there had been water problems since February 2012. During an interview in the conference room on 10/16/12 at 4:55 PM when the Director of Operations was asked if she felt the patients had been at risk for any problems related to the water, she stated, "...we looked at infections... looked at validations... did seek and try to resolve it... [have] piece of mind in that dialysate is clear..." During a telephone interview in the conference on	V 627		

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V 627	Continued From page 58 10/18/12 at 3:00 PM, the surveyor asked the Medical Director if he was aware of the issues with the water culture and endotoxin levels being out-of-range for the past year. The Medical Director stated he was aware. Refer to V179 and V274.	V 627		
V 634	494.110(a)(2)(vi) QAPI-INDICATOR-MEDICAL INJURIES/ERRORS The program must include, but not be limited to, the following: (vi) Medical injuries and medical errors identification. This STANDARD is not met as evidenced by: Based on policy review, meeting minutes, document review, medical record review, observation and interview, the facility failed to ensure the QAPI committee identified and took action to minimize the number of occurrences and limit the number of patients affected by staff failure to follow facility policies and procedures for monitoring patients during hemodialysis treatments and failure of patients to maintain vascular access site visibility during treatments for 13 of 17 (Patients #1, 2, 3, 4, 6, 7, 8, 9, 11, 13, 14, 15, and 17) sampled patients and 4 (RP #1, 2, 3, and 4) random patients observed. The facility's failure to identify and address these problems resulted in SERIOUS AND IMMEDIATE THREAT to the health and safety of all the hemodialysis patients and placed them at risk for the potential of death and other complications. The continued disregard for adherence to policy and procedure without intervention by the QAI	V 634		

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V 634	Continued From page 59 committee demonstrated the IMMEDIATE JEOPARDY continues. The findings included: 1. Review of the facility's "Quality Assessment and Performance Improvement Program" policy revealed, "The Quality Assessment and Performance Improvement (QAI) Program encompasses all aspects of patient care... The QAI Program is designed and implemented to objectively, systematically, and comprehensively monitor, evaluate, and improve the quality and appropriateness of patient care and services by identifying opportunities and resolving identified problems... Improvement projects will be prioritized by the QAI Committee... Examples of urgent priorities... Failure to provide adequate observation of patient, patient vascular access, or patient equipment." 2. Review of the facility's "Patient Monitoring During Patient Treatment" policy revealed, "... Vital signs will be monitored at the initiation of dialysis and every 30 minutes, or more frequently as needed... Observe and document at the initiation of dialysis and at every safety check that all connections are secure and visible... Ensure that bloodlines are secured to the patients... Ensure access remains uncovered throughout the treatment... Documentation of monitoring will be completed on the treatment record..." Review of the facility's "Patient Safety Checks" policy revealed, "... The purpose of this policy is to provide guidance on safety checks to prevent, detect and treat complications... Safety checks will be performed pre treatment and every 30	V 634		

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V 634	Continued From page 60 minutes or more frequently as needed once the treatment has begun. CAUTION: VASCULAR ACCESS, NEEDLE/CATHETER INSERTION SITES, BLOODLINE CONNECTIONS AND PATIENT'S FACES SHOULD BE VISIBLE AT ALL TIMES..." Review of the facility's "Patient Evaluation Pre Dialysis Treatment" policy revealed, "...patient care staff will complete a pre dialysis evaluation prior to initiation of patient treatment... Patient assessment is a nursing responsibility and cannot be delegated to unlicensed patient care staff... The assessment must be documented in the patient's medical record... " 3. Medical record review for Patients #1, 2, 3, 4, 6, 7, 8, 9, 11, 13, 14, 15, and 17 from 1/20/12 through 10/15/12 revealed 9 incidents of the preassessment being performed after treatment had been initiated, 42 incidents of VS not being performed and documented timely according to policy and 20 incidents of safety checks not being performed and documented according to policy. 4. Medical record review for Pt #7 revealed her 9/18/12 treatment was started at 9:43 AM and the Pre-Treatment Nursing Assessment was completed at 9:46 AM (after the start of the treatment). There was no documentation of vital signs, access checks or safety checks from 9:43 AM until 11:12 AM when the PCT documented the patient's vital signs (BP-100/68 P-117) and that the patient was alert and resting comfortably. At 12:07 PM, vital signs were documented (BP-94/70 P-114) by the PCT and that the patient was, "alert, denies complaints, resting	V 634		

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V 634	Continued From page 61 comfortably." The Post Dialysis Vitals and Evaluation section of the Treatment Record documented, "Post vitals unable to complete-patient emergency." The Nursing Evaluation documented, "...at aprox 1210 pt became non responsive... Aprox 1500 ml blood loss." Review of the facility's event form dated 9/26/12 revealed, "During initiation of CPR it was noted that the venous needle and line had become separated and the patient had experienced blood loss..." During a telephone interview on 10/23/12 at 2:10 PM, PCT #5 stated, [Pt #7] always kept her access covered. She said she was cold." 5. Observations on 10/15/12 beginning at 1:45 PM revealed Pt #14 receiving hemodialysis with his access covered by the sleeve of his shirt. Observations on 10/15/12 beginning at 1:52 PM revealed RP #1 was covered with a blanket from the knees to shoulders. The patient was continuously observed from 1:52 PM to 3:10 PM and the staff did not uncover or assess the patient's access site or line connections. Observations on 10/15/12 beginning at 2:17 PM revealed RP #2 notified the PCT that she was cramping. The nurse was observed to give the patient a normal saline bolus. During this time the patient's access site was covered with a quilt. Neither the nurse nor the PCT uncovered the access site. Observations on 10/17/12 beginning at 8:20 AM revealed RP #3 and RP #4 were receiving hemodialysis treatment with their access sites	V 634		

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V 634	Continued From page 62 covered by a blanket. 6. Review of the Adverse Event Summary for Hemodialysis for 2012 documented 8 patients with blood loss >100 ml from February 2012 through September 2012. 7. Review of the QAI meeting minutes from 3/16/12 (February 2012) until September 2012 revealed the QAI committee failed to identify staff failure to adhere to facility policy for monitoring patients during hemodialysis treatment, failure to ensure visibility of vascular access during hemodialysis treatment, or blood loss as areas for improvement.	V 634		
V 692	494.140(e)(1),(2) PQ-PCT-STATE REQUIREMENTS & HS DIPLOMA Patient care dialysis technicians must- (1) Meet all applicable State requirements for education, training, credentialing, competency, standards of practice, certification, and licensure in the State in which he or she is employed as a dialysis technician; and (2) Have a high school diploma or equivalency; This STANDARD is not met as evidenced by: Based on Tennessee Code for Practice of Professional Nursing, medical record review and interview, the facility failed to monitor PCT's to assure they did not administered NS to 2 of 17 (Patient ' s #8 and #13) sampled patients. The findings included: 1. Tennessee Code Annotated 63-7-103 Practice of Professional Nursing Defined (a) (1) documented, "Practice of professional nursing	V 692		

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V 692	Continued From page 63 means the performance for compensation of any act requiring substantial specialized judgement and skill based on knowledge of the natural, behavioral and nursing sciences, and the humanities, as the basis for application of the nursing process in wellness and illness care." Review of the Tennessee Board of Nursing Position Statement RE: Practice: Deligation of Medication Administration documented, "Authority: Tennessee Code Annotated 63-7-101 (license required to practice nursing)...Position: The Tennessee Board of Nursing will not approve a program for unlicensed persons to administer medication since such would reduce the quality of care which exists and may lower standards as recognized..." 2. Medical record review for Patient #8 revealed on 6/1/12 PCT #1 documented, "c/o cramping - uf goal is cut back to minimum 300 cc NS is given by RN's advice continue to monitor." 3. Medical record review for Patient #13 revealed on 5/10/12 at 9:17 AM, PCT #2 documented, "bp low 100 cc n/s rins [rinse] back. Cut uf to min." Review of the treatment sheet dated 5/12/12 revealed PCT #3 documented, "pt b/p is 92/67 rn requested that the pt goal be reduced to minimum and 150 cc of saline be given." 4. In an interview at the nurses' station on 10/9/12 at 2:45 PM, the Director of Operations verified that the PCT gave NS per documentation.	V 692		
V 710	494.150 CFC-RESPONSIBILITIES OF THE MEDICAL DIRECTOR	V 710		

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V 710	Continued From page 64 This CONDITION is not met as evidenced by: Based on Governing Bylaws, facility policy and procedure, document review, medical record review, observation and interview, the Medical Director failed to demonstrate responsibility for ensuring delivery of quality patient care and clinical outcomes. The Medical Director's failure to ensure water quality was maintained, POC's were individualized and revised to reflect current patient safety issues, QAPI identified and corrected serious problems and staff adherence to policies and procedures resulted in a SERIOUS AND IMMEDIATE THREAT to the health and safety of all facility hemodialysis patients. Review and observations during the survey revealed these issues have not been corrected and demonstrates the IMMEDIATE JEOPARDY continues. The findings included: 1. The Medical Director failed to ensure the quality of the water used to prepare dialysate had water culture and endotoxin levels below the action levels and failed to ensure a cause for the continued elevated levels was identified and effective corrective actions were implemented and the problem resolved. Refer to V179, V274 and V627. 2. The Medical Director failed to ensure policies and procedures were followed for hemodialysis accesses sites and blood line connections to remain visible and monitored during treatment. Refer to V407	V 710		

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V 710	Continued From page 65 3. The Medical Director failed to ensure POC's were individualized to include concerns for visibility and monitoring of patient's during treatment. Refer to V543 and V559 4. The Medical Director failed to ensure the QAPI committee identified variances and developed and implemented a corrective action plan to ensure the health and safety of all patients receiving hemodialysis. Refer to V634 and V712. 5. The Medical Director failed to ensure staff adhered to facility policies and procedures. Refer to V190, V407, V504, V547, V556 and V557.	V 710		
V 712	494.150(a) MD RESP-QAPI PROGRAM Medical director responsibilities include, but are not limited to, the following: (a) Quality assessment and performance improvement program. This STANDARD is not met as evidenced by: Based on policy review, meeting minutes review, document review, medical record review and interview, the Medical Director failed to ensure the QAPI committee developed and implemented action plans to ensure the health and safety of patients receiving hemodialysis. The Medical Director's failure to demonstrate responsibility for QAPI intervention to maintain the water treatment system and to ensure adherence to facility policies and procedures resulted in a SERIOUS AND IMMEDIATE THREAT to the health and safety of all the	V 712		

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V 712	Continued From page 66	V 712		

patients receiving hemodialysis.

The findings included:

1. Review of the facility's policy "Quality Assessment and Performance Improvement Program (QAPI)" revealed "... The Medical Director is th Chairperson of the QAI Committee and is responsible for the overall effectiveness of the facility QAI Program and communication with the Governing Body of the status of QAI activities... The Medical Director will communicate with the Governing Body regarding QAI activities. The Governing Body will review information related to significant problems identified and their causes, and provide guidance and support for proposed needed corrections..."

Review of the facility's Bylaws revealed, "...Medical Director Duties. The Medical Director is directly and actively responsible for the creation, on-going improvement and preservation of high quality professional care of patients at the Facility... The Medical Director is responsible for the delivery of patient care and outcomes in the Facility..."

Review of the facility's policy, "Microbiological Monitoring of Water Used for Dialysis Purposes" revealed, "....Test results exceeding the Action Level or allowable limits - Promptly (within 48 hours) notify the Medical Director...Discuss with Medical Director, the creation of an action plan when test results indicate that the "Allowable limits" have been exceeded..."

Review of the bacterial cultures and endotoxin testing results and disinfection logs for the water

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V 712	Continued From page 67 treatment system during the months of 4/11, 5/11, 6/11, 7/11, 8/11, 9/11, 10/11, 11/11, 12/11, 1/12, 2/12, 3/12, 4/12, 5/12, 6/12, 7/12, 8/12, 9/12 and 10/12 revealed culture and/or endotoxin levels outside the allowable and/or action limits. There was no documentation the Medical Director reviewed and monitored the elevated water cultures. During a telephone interview from the conference room on 10/18/12 at 3:00 PM, the surveyor asked the Medical Director if he was aware of the issues with the water culture and endotoxin levels being out-of-range for the past year. The Medical Director stated he was aware. Review of the QAI meeting minutes dated 7/11, 8/11, 9/11, 10/11, 11/11, 12/11, 1/12, 2/12, 3/12, 4/12, 5/12, 6/12, 7/12 and 9/12 revealed no documentation the elevated water cultures and endotoxin levels were tracked and trended to determine a root cause for the continued elevated water cultures and endotoxin levels. There was no documentation an action plan was developed and implemented to ensure the water cultures and endotoxins were maintained within the acceptable parameters. Attached to the QAPI meeting minutes were communication summaries used by the technicians to show the summary of water cultures and endotoxin levels elevated outside of the allowable limits. Under the section of the QAPI meeting minutes titled, "Water/Dialysate Quality Monitoring: Microbiology and Water Chemical Analysis" in the area stating "Is disinfection required more than	V 712		

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V 712	Continued From page 68 monthly...", the answer was marked "No"; the area titled "Improvement Area" was marked "No." 2. Review of the facility's "Patient Monitoring During Patient Treatment" policy revealed, "... Vital signs will be monitored at the initiation of dialysis and every 30 minutes, or more frequently as needed... Observe and document at the initiation of dialysis and at every safety check that all connections are secure and visible... Ensure that bloodlines are secured to the patients... Ensure access remains uncovered throughout the treatment... Documentation of monitoring will be completed on the treatment record..." Review of the facility's "Patient Safety Checks" policy revealed, "... The purpose of this policy is to provide guidance on safety checks to prevent, detect and treat complications... Safety checks will be performed pre treatment and every 30 minutes or more frequently as needed once the treatment has begun. CAUTION: VASCULAR ACCESS, NEEDLE/CATHETER INSERTION SITES, BLOODLINE CONNECTIONS AND PATIENT'S FACES SHOULD BE VISIBLE AT ALL TIMES..." Medical record review for Patients #1, 2, 3, 4, 6, 7, 8, 9, 11, 13, 14, 15, and 17 from 1/20/12 through 10/15/12 revealed 42 incidents of VS not being performed and documented timely according to policy and 20 incidents of safety checks not being performed and documented according to policy. Medical record review for Pt #7 revealed her 9/18/12 treatment was started at 9:43 AM and the Pre-Treatment Nursing Assessment was	V 712		

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V 712	Continued From page 69 completed at 9:46 AM (after the start of the treatment). There was no documentation of vital signs, access checks or safety checks from 9:43 AM until 11:12 AM when the PCT documented the patient's vital signs (BP-100/68 P-117) and that the patient was alert and resting comfortably. At 12:07 PM, vital signs were documented (BP-94/70 P-114) by the PCT and that the patient was, "alert, denies complaints, resting comfortably." The Post Dialysis Vitals and Evaluation section of the Treatment Record documented, "Post vitals unable to complete-patient emergency." The Nursing Evaluation documented, "...at aprox 1210 pt became non responsive... Aprox 1500 ml blood loss." Review of the facility's event form dated 9/26/12 revealed, "During initiation of CPR it was noted that the venous needle and line had become separated and the patient had experienced blood loss..." During a telephone interview on 10/23/12 at 2:10 PM, PCT #5 stated, [Pt #7] always kept her access covered. She said she was cold." Observations on 10/15/12 beginning at 1:45 PM revealed Pt #14 receiving hemodialysis with his access covered by the sleeve of his shirt. Observations on 10/15/12 beginning at 1:52 PM revealed RP #1 was covered with a blanket from the knees to shoulders. The patient was continuously observed from 1:52 PM to 3:10 PM and the staff did not uncover or assess the patient's access site or line connections. Observations on 10/15/12 beginning at 2:17 PM	V 712		

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V 712	Continued From page 70 revealed RP #2 notified the PCT that she was cramping. The nurse was observed to give the patient a normal saline bolus. During this time the patient's access site was covered with a quilt. Neither the nurse nor the PCT uncovered the access site. Observations on 10/17/12 beginning at 8:20 AM revealed RP #3 and RP #4 were receiving hemodialysis treatment with their access sites covered by a blanket. Review of the Adverse Event Summary for Hemodialysis for 2012 documented 8 patients with blood loss >100 ml from February 2012 through September 2012. Review of the QAI meeting minutes from 3/16/12 (February 2012) until September 2012 revealed the QAI committee failed to identify staff failure to adhere to facility policy for monitoring patients during hemodialysis treatment, failure to ensure visibility of vascular access during hemodialysis treatment, or blood loss as areas for improvement.	V 712		
V 715	494.150(c)(2)(i) MD RESP-ENSURE ALL ADHERE TO P&P The medical director must- (2) Ensure that- (i) All policies and procedures relative to patient admissions, patient care, infection control, and safety are adhered to by all individuals who treat patients in the facility, including attending physicians and nonphysician providers; This STANDARD is not met as evidenced by:	V 715		

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V 715	Continued From page 71 Based on Bylaws review, facility policy review, medical record review, observation and interview, the Medical Director failed to ensure staff adhered to facility policies and procedures for medication preparation, vascular access visualization, monitoring during treatment, B/P and cramping management and Heparin administration. The Medical Director's failure to demonstrate responsibility for staff adherence to policies and procedures concerning vascular access visibility and monitoring of patient's during treatment resulted in SERIOUS AND IMMEDIATE THREAT to the health and safety of all the patients receiving hemodialysis at the facility. The findings included: 1. Review of the facility By-laws revealed, "...The Medical Director is responsible for the delivery of patient care and outcomes in the Facility and is accountable to the Company [company initials], Medical Department, Governing Body and CMS, for the quality of medical care provided to patients... Ensure that all policies and procedures relative to patient admissions, patient care (including, but not limited to, patient comprehensive assessments, plans of care and patient rights and responsibilities), infection control, and safety are made available to all medical staff members and non-physician practitioners and that they are adhered to by all individuals who treat patients in the Facility..." 2. Review of the facility policy and procedure, "Medication Preparation and Administration" revealed, "Labeling Vials: When preparing	V 715		

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medications if the vial is not used immediately in its entirety, the nurse must place the date and time the vial was opened on the medication label along with the nurse initials."

Observations during a tour of the treatment area on 10/15/12 at 1:45 PM at machine #20 revealed a syringe filled with a clear liquid was infusing. There was no label on the syringe indicating what was inside, when it was drawn up or whom. Observations in the locked medication drawer during tour of the treatment area on 10/15/12 at 2:42 PM revealed syringes for 11 different patients labeled with the medication name, patient names and the date 0/15/12. There was no time or initials to indicate who drew the medication into the syringes.

During an interview in the conference room on 10/18/12 at 10:20 AM the Director of Operations verified the correct procedure for medication administration is to label the drugs with name, initials and time the medication was drawn into the syringe.

3. Review of facility policies, "Patient Monitoring During Patient Treatment", Patient Safety Checks", facility incident report, medical record review and interview revealed the Medical Director failed to ensure the policies and procedures visual monitoring of the vascular access and bloodline connections, VS and safety checks.
Failure of the Medical Director to ensure the policies and procedures for monitoring patients during hemodialysis treatment resulted in Pt #7 experiencing excessive blood loss.
Refer to V407 and V543.

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V 715	Continued From page 73 4. Review of facility policies "Blood Pressure Management Treatment Parameters"and "Treatment of Muscle Cramping" revealed the Medical Director failed to ensure patients who experienced hypertension or hypotension, and/or muscle cramping during hemodialysis treatment were treated according to policy. Refer to V 504. 5. Review of facility policy "Comprehensive Interdisciplinary Assessment and Plan of Care" revealed the Medical Director failed to ensure staff followed facility policies and procedures to individualize the POC for Pt #7's covered vascular accesses and bloodlines durring the dialysis treatment. Refer to V543 and V559. 6. Review of the facility "Heparinization" policy revealed the Medical Director failed to ensure the staff discontinued heparin infusion according to policy. Refer to V547.	V 715		
V 750	494.180 CFC-GOVERNANCE This CONDITION is not met as evidenced by: Based on Bylaws, Governing Body meeting minutes, policy review, medical record review, water culture and endotoxin levels, disinfection logs, observation and interview, the Governing Body failed to ensure water used to prepare dialysate was maintained below action level to ensure health and safety of patients who received hemodialysis and failed to find a cause for the continued elevated bacterial cultures and endotoxins, maintain visibility and monitor patient	V 750		

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accesses during treatment, and ensure the facility followed policies and procedures to ensure the health and safety of all patients who received hemodialysis at the facility.

The Governing Body's failure to ensure the water was free of bacteria, POC's were individualized to address the current needs of the patient, QAPI program identified issues and put actions into place for correction and staff adherence to policies and procedures resulted in a SERIOUS AND IMMEDIATE THREAT to the health and safety of all patients receiving dialysis. Record review, observations and interviews during the survey revealed these occurrences had not been corrected and demonstrated the IMMEDIATE JEOPARDY situation continues.

The findings included:

1. The Governing Body failed to ensure processes were followed to determine the cause of recurrent elevated levels of bacteria and endotoxins in the water used to prepare dialysate and ensure the levels were maintained below action levels to ensure the health and safety of all patients who received hemodialysis in the facility.
Refer to V179, V274 and V627.

2. The Governing Body failed to ensure patients' hemodialysis accesses were visible and monitored throughout treatment.
Refer to V407.

3. The Governing Body failed to ensure the patient's POC was individualized to address covered hemodialysis access during treatment.
Refer to V543 and V559.

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V 750	Continued From page 75 4. The Governing Body failed to ensure the QAPI committee trended events that compromised the health and safety of all patients and put action plans in place to ensure the health and safetyof all patients receiving hemodialysis. Refer to V634 and V712. 5. The Governing Body failed to ensure staff followed facility policies and procedures to maintain the health and safety of all patients who received hemodialysis. Refer to V407, V504, V543, V547, V559, and V557.	V 750		